Claim 2. (Amended) [The A composition comprising a live non-encapsulated attenuated [of claim 1, wherein said] Streptococcus equi [is non-encapsulated] in combination with an immunostimulant, the immunostimulant having the property of stimulating mucosal immunity.

In claims 3-5 and 9, line 1 in each, delete "1" and insert - -2- -.

In claim 1/1, line 3, delete "1" and insert - -2- -.

REMARKS

Claims 1-21 are under consideration in this application. Claims 1, 2, 5, 10, 15, 17 and 19-21 stand rejected under 35 U.S.C. 102(b). Claims 1, 3, 10, 17, and 19-21 stand rejected under 35 U.S.C. 102(a). Claims 1-21 stand rejected under 35 U.S.C. 103(a). Claim 1 is canceled. Claim 2 is amended to incorporate all of the recitations of claim 1. Claims 3-5, 9 and 17 are amended to correct the dependency from canceled claim 1 to newly amended independent claim 2.

Reconsideration of this application is respectfully requested.

Prior to addressing the rejections, applicant wishes to clarify a number of events which took place during prosecution. A first Amendment After Final Under Rule 116 in response to the May 21, 1999 Final Office Action was filed on August 20, 1999 following a

Amendment

Serial No.: 09/007,385

telephone interview with Examiner Weatherspoon on May 25, 1999. On October 15, 1999, the undersigned received a telephone message from Examiner Weatherspoon stating that he was looking at the Amendment and would be entering an Interview Summary Record. No Action or Interview Summary Record was ever received following this telephone message. On November 8, 1999, the undersigned attempted to call the Examiner and was informed that he had left the Patent Office. On this same date, the undersigned telephoned and spoke to Supervisory Primary Examiner Anthony Caputa who stated he would order the file, look into the case and telephone. On November 22, 1999, the undersigned telephoned Examiner Caputa, whose voice mail stated that he would be out for the Thanksgiving holiday.

A Three Month Extension of Time and a Notice of Appeal is being filed concurrently with this Supplemental Amendment After Final.

Below is a discussion of the outstanding rejections presented by Examiner Weatherspoon in the May 21, 1998 Final Office Action along with a discussion of the amendments presented herein.

REJECTIONS UNDER 35 U.S.C. § 102(b)

The Examiner maintains his rejection of claims 1, 2, 5, 10, 15, 17 and 19-21 under 35 U.S.C. 102(b) as being anticipated by either Timoney (U.S. Patent No. 5,183,659) ("'659 patent") or Timoney (PCT WO 87/00436) ("'436 PCT"). The Examiner contends that the claimed invention does not recite an immunostimulant to be administered in addition to live attenuated virus. Applicant respectfully traverses the rejection.

Amendment

Serial No.: 09/007,385

As noted in the Amendment After Final filed August 20, 1999, during a May 25, 1999 telephone call between the undersigned and the Examiner, the fact that the M protein of the Timoney references is part of the S. equi bacterial strain 709-27 and is not an additional immunostimulant added to enhance the immunogenicity of the vaccine as claimed was discussed. The Examiner suggested adding language from the Specification at page 3, line 27 to replace "and" with "in combination with."

Applicant notes that claim 1 has been canceled. Claim 2 has been amended to incorporate all of the recitations of claim 1 and, as suggested by the Examiner, the claim reads as "A composition comprising a live non-encapsulated attenuated Streptococcus equi in combination with an immunostimulant..."

In light of the foregoing remarks, cancelation and amendment, applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1 and 2 under 35 U.S.C. 102(b). In addition, since claims 5, 10, 15, 17 and 19-21 contain all of the limitations, features and attributes of claim 2, applicant respectfully submits that these claims are also not anticipated over the cited art. In re Fine, 5 U.S.P.Q. 2d 1596, 1600 (Fed. Cir. 1988).

REJECTIONS UNDER 35 U.S.C. § 102(a)

The Examiner maintains his rejection of claims 1, 3, 10, 17 and 19-21 under 35 U.S.C. 102(a) as being anticipated by Hartford et al (European Patent Application No. EP 0 786 518 Al) ("Hartford"). While applicant disagrees with the Examiner in that Hartford

nowhere discloses that its vaccine eleicits protective immunity in a horse, in the interest of expediting prosecution and allowance of the claims, applicant notes that claim 1 has been canceled and claims 3, 10, 17 and 19-21 each depend from newly amended independent claim 2.

In light of the foregoing, applicant respectfully submits that the rejection of claim 1, now canceled, has been rendered moot. In addition, in light of the fact that claims 3, 10, 17 and 19-21 each now depend from claim 2 which was not rejected in view of Hartford, applicant respectfully submits that they are in no way anticipated by the cited art.

REJECTIONS UNDER 35 U.S.C. § 103(a)

The Examiner maintains his rejection of claims 1-21 under 35 U.S.C. 103(a) over Timoney or Timoney in view of Hartford and Gerber (U.S. Patent No. 4,806,350) ("Gerber"). Applicant respectfully traverses the rejection.

As noted above, claim 1 has been canceled and each of claims 3-21 now depend from newly amended claim 2. Claim 2 recites a separate immunostimulant, namely, a composition comprising a live non-encapsulated attenuated *Streptococcus equi* in combination with an immunostimulant. Claims 3-21 incorporate all of the limitations of claim 2.

Neither the Timoney nor the Hartford references apply to the invention as claimed. The Timoney M protein is "retained on" the Streptococcus equi, i.e., the M protein is part of the S. equi bacterium and is not a separate immunostimulant. The Timoney references do not suggest or motivate the reader to incorporate an immunostimilant in

Amendment

Serial No.: 09/007,385

combination with the live Streptococcus equi. The Hartford reference neither teaches nor suggests a non-encapsulated Streptococcus equi. A person of ordinary skill in the art would not be motivated to make the composition comprising a live non-encapsulated attenuated Streptococcus equi in combination with an immunostimulant as claimed.

With regard to Gerber, while the reference does teach the use of saponin as an adjuvant, nowhere does it motivate the reader to use it as an immunostimulant in combination with the live non-encapsulated attenuated *Streptococcus equi* for stimulating mucosal immunity as claimed herein. Gerber nowhere makes up for the deficiencies of Timoney and Hartford.

In light of the cancellation of claim 1 and the foregoing remarks, applicant respectfully requests reconsideration and withdrawal of the rejection of claim 1 and 2 under 35 U.S.C. 103(a). In addition, since claims 3-21 each contain all of the limitations, features and attributes of claim 2, these claims should also be found non-obvious over the cited art. In re Fine, 5 U.S.P.Q. 2d 1596, 1600 (Fed. Cir. 1988).

CONCLUSION

In light of the foregoing, reconsideration and withdrawal of all of the objections and rejections are respectfully requested. Applicant submits that all of claims 2-21 are in condition for allowance. Prompt and favorable allowance of the claims is requested. If for any reason the Examiner concludes that any of the claims as amended is not properly

allowable, the Examiner is respectfully requested to contact the undersigned by telephone at 212-527-7679.

Respectfully submitted,

Anne E. Zitron, Ph.D.

Reg. No. 41,391 Agent for Applicant

DARBY & DARBY P.C. 805 Third Avenue, 27th Floor New York, New York 10022 (212) 527-7700